RESEARCH ARTICLE JSLS

Evaluation of a Novel Trocar-Site Closure Device in Laparoscopic Surgery

Youngbae Jeon, MD, Soohwa Song, PhD, Kyoung-Won Han, MD, Dong-Hyuk Lee, PhD, Jeong-Heum Baek, MD, PhD

ABSTRACT

Background and Objectives: We evaluated the effectiveness and safety of EZ-Close™ compared to those of hand suture for trocar-site closure according to obesity.

Methods: Fifty-four cases of laparoscopic colorectal surgery were enrolled. For the same patient, the right port site was closed using EZ-Close™ and left port site was closed by hand suture among cases with port-site diameter ≥10 mm. Cases switched to use of a conventional fascial closure device or with closure time 120 s were considered failures. Closure time was analyzed according to body mass index (BMI) and abdominal wall thickness (AWT).

Results: The mean closure time was significantly shorter with EZ-Close™ than with hand suture (87.9 ± 21.0 vs. 128.0 ± 59.0 s, $p < 0.001$). The number of failure cases was significantly lower with EZ-Close™ than with hand suture (7 vs. 27, $p < 0.001$). The closure time of EZ-Close™ was significantly shorter than that of hand suture in patients with BMI ≥ 25 and < 27 kg/m^2 (n = 15, 85.9 ± 19.8 vs. 135.6 ± 67.9 s, $p < 0.014$) and ≥ 27 kg/m^2 (n = 13, 85.1 ± 18.4 vs. 150.2 ± 70.6 s, $p < 0.010$). With respect to AWT, the closure time of EZ-Close™ was significantly shorter than that of hand suture in patients with AWT ≥ 20 and < 26 mm (n = 12, 81.1 ± 11.5 vs. 142.3 ± 83.7 s, $p = 0.023$) and ≥ 26 mm (n = 17, 85.6 ± 22.6 vs. 160.2 ± 55.5, $p < 0.001$). No infection and herniation were detected in both trocar sites during the follow-up period (median 20.4 months).

Conclusion: EZ-Close™ could provide time efficiency in trocar-site closure, especially in obese patients.

Keywords: Trocar-site closure, Laparoscopic colorectal surgery, Body mass index.

INTRODUCTION

Since the introduction of the laparoscopy in the 20th century, its use has rapidly become widespread. Compared with open surgery, the laparoscopic approach has several benefits including less pain, smaller incisions, shorter hospitalization, and better postoperative recovery with comparable oncologic safety.[1–3] Currently, laparoscopic surgery is considered an alternative treatment method for patients with locally advanced colorectal cancer.[4] Trocar insertion is a routine first step in laparoscopic surgery; however, incomplete closure of the fascial layer can lead to trocar-site herniation. Although the incidence of trocar-site herniation after laparoscopic surgery was reported to be between 0.5% and 5.2%, the actual incidence may be higher when taking into account asymptomatic patient.[5–7] Furthermore, trocar-site herniation is sometimes associated with serious complications, such as bowel strangulation, which requires reoperation. Thus, when using a trocar with diameter of >10 mm, fascial closure is recommended to prevent trocar-site herniation.[8–10]

Most surgeons generally close the trocar site by hand suturing. However, the closure time and accuracy are affected by the surgeon's skill level and patients' obesity. Obese patients have a relatively thick abdominal wall, which makes closure of the port site technically difficult

Department of Surgery, Gil Medical Center, Gachon University College of Medicine, Incheon, Republic of Korea (Drs Jeon, Han and Baek).

Department of Biomedical Engineering, Gachon University College of Medicine, Incheon, Republic of Korea (Drs Song and Lee).

Youngbae Jeon and Soohwa Song equally contributed as first authors.

This article was presented as an e-poster at the 39th Congress of the European Society of Surgical Oncology, Rotterdam, the Netherlands, October 9–11, 2019.

Disclosures: none.

Funding/Financial Support: This research was supported by a grant from the Korea Health Technology R&D Project through the Korea Health Industry Development Institute, funded by the Ministry of Health & Welfare, Republic of Korea (grant no. HI16C2319).

Conflicts of Interest: The authors have no conflicts of interest directly relevant to the content of this article.

Acknowledgements: We would like to thank Editage (http://www.editage.co.kr) for English language editing.

Informed consent: Dr. Baek declares that written informed consent was obtained from the patient/s for publication of this study/report and any accompanying images.

Address correspondence to: Jeong-Heum Baek, MD, PhD, Gachon University Gil Medical Center 21 Namdong-daero 774 Beon-gil, Namdong-gu Incheon, Republic of Korea, 21565. Tel: +82–10-8608–708, E-mail: gsbaek@gilhospital.com

DOI: 10.4293/JSLS.2020.00033

owing to the limited visual field despite using a retractor and take a longer time than in nonobese patients. Furthermore, the incidence of trocar-site herniation increases by up to 6.3% in patients with body mass index (BMI) > 30 kg/m^2.[11] Therefore, the development of a convenient device that can help close the port site easily, precisely, and uniformly, even in patients with a thick abdominal wall, is needed. Recently, a new trocar-site closure device for a quick and simple closure of the abdominal trocar site after laparoscopic surgery has been developed. This study aimed to evaluate the effectiveness of the newly developed suture device compared with those of the hand suture method for trocar holes 10 mm in laparoscopic colorectal surgery.

MATERIALS AND METHODS

Patient Selection

This study was prospectively designed to include patients scheduled to undergo laparoscopic colorectal surgery (anterior resection or low anterior resection) using a ≥10 mm trocar on both sides of the abdomen. Patients with BMI < 22 or > 35 kg/m^2, those with a history of hernia repair, and those requiring emergency surgery were excluded. Finally, 54 patients undergoing laparoscopic colorectal surgery were prospectively enrolled in the study. Institutional review board approval was obtained from the ethics committee of Gil Medical Center, and all experiments were conducted in accordance with the Declaration of Helsinki (approval no. GDIRB2017–223).

Experimental Instrument for Laparoscopic Port-Site Closure

A port-site suturing device (EZ-Close™; Medical Impact Inc., Bucheon, Republic of Korea) consisting of a body, cartridge, and anchor needle, was newly developed (**Figure 1**). For using this instrument, the body and cartridge are combined and inserted into the trocar site. Thereafter, absorbent suture, which is mounted in the cartridge inserted under the peritoneum, is pulled up using the anchor needle through both symmetrical channels of the instrument. Finally, the device is removed and a buried suture is tied to uniformly close the peritoneum and fascia layer. All fascial closures were performed by 3rd to 4th year general surgical residents who had no previous experience with the novel closure device.

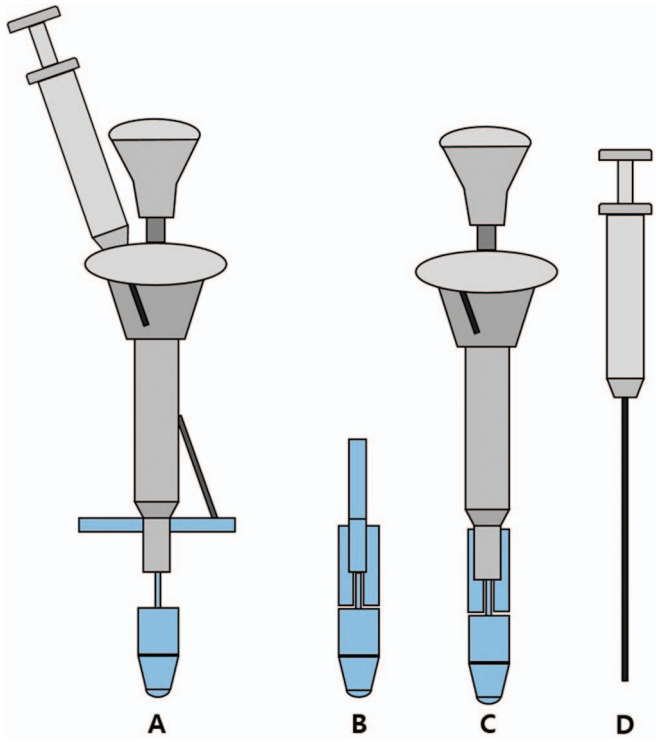

Figure 1. A. Diagram of the EZ-Close™ port-site closure system (combined form). **B**. Diagram of the cartridge. **C**. Diagram of the body. **D**. Diagram of the anchor needle.

Study Design and Assessment Parameters

For the same patient, the right port site was closed using EZ-Close™ and the left port site was closed by hand suture among cases with a port-site diameter of ≥10 mm. Cases switched to use of a conventional device for fascial closure (BERCI fascial closure instrument; Karl Storz Inc., Tuttlingen, Germany), or those with a closure time of >120 s were counted as failure cases. The closure time was defined as the time from the first grip of EZ-Close™ or needle holder to the complete suture tie of the peritoneum and fascia layers.

We examined the differences in closure time, number of attempts, and number of failures between the use of the suturing device and the use of hand suture. The patients were followed up at 6 weeks after surgery and assessed for short-term wound complications including hematoma, herniation, and infection. The late onset trocar-site hernia was checked based on the follow-up abdominopelvic computed tomography and outpatient medical records. The difference in closure time according to BMI and abdominal wall thickness (AWT) was analyzed. The AWT was measured at the level of the trocar insertion site by using abdominopelvic

computed tomography images. The obesity in this study was defined as BMI ≥25 kg/m^2 according to the criteria of Asia-Pacific perspective in World Health Organization.[12] The patients were divided into four subgroups according to BMI (<23, 23–24.9, 25–26.9, and ≥27 kg/m^2) and four subgroups according to AWT (<16, 16–19.9, 20–25.9, and ≥26 mm). The significant differences of each variable between the suturing device and the hand suture method were evaluated using paired t-tests. All statistical analyses were performed with IBM SPSS Statistics 17 for Windows (IBM SPSS Inc., Chicago, IL, USA).

RESULTS

A total of 54 patients including 35 men and 19 women were enrolled. The mean ± standard deviation age was 62.7 ± 11.7 years, and 11 (20.4%) patients had a history of abdominal surgery. The mean BMI and AWT were 25.0 ± 2.8 kg/m^2 and 22.3 ± 7.7 mm, respectively. The mean intraoperative estimated blood loss was 55.3 ± 55.1 mL, and the mean operative time was 116.9 ± 28.1 min. The patients were discharged 7.8 ± 2.4 days after surgery, on average. No infection and herniation were observed in all patients at postoperative 6 weeks short-term assessment. Late-onset herniation was also not detected in both groups during the follow-up periods (median 20.4 months, range 1.3 ~ 30.6 months). The patient demographics and perioperative outcomes are demonstrated in (**Table 1**). (**Table 2**) shows the comparison between right port sites closed using EZ-Close™ and left port sites closed using hand suture. No significant difference in AWT was found between the sides (22.4 ± 7.9 vs. 22.1 ± 7.6, mm, $p = 0.153$). The number of attempts of complete closure between the suturing device and the hand suture method also showed no statistical difference (1.1 ± 0.2 vs. 1.1 ± 0.3, $p = 0.742$). The number of failure cases with EZ-Close™ was significantly fewer than that with hand suture (n = 7, 13% vs. n = 27, 50%, $p < 0.001$). The right port side, in which EZ-Close™ was used, showed a shorter mean closure time than the left port side (87.9 ± 21.0 vs. 128.0 ± 59.0 s, $p < 0.001$). Among the hand suture cases, the failure group had significantly higher BMI ($p = 0.036$) and thicker AWT ($p < 0.001$) than the success group (**Table 3**).

(**Table 4**) and (**Figure 2**) show the difference in closure time between the right and left port sides according to BMI and AWT. The closure time with EZ-Close™ was significantly shorter than that with hand suture in patients with 25 ≤ BMI < 27 kg/m^2 (n = 15, 85.9 ± 19.8 vs. 135.6 ± 67.9 s, $p < 0.014$) and those with BMI ≥ 27 kg/m^2 (n = 13, 85.1 ± 18.4 vs. 150.2 ± 70.6 s, $p < 0.01$).

Table 1.
Perioperative Patient Demographics and Perioperative Outcomes

Variables	Total Patients
	(n = 54)
Age, mean ± SD, years	62.7 ± 11.7
Sex, n (%)	
Male	35 (64.8)
Female	19 (35.2)
BMI, mean ± SD, kg/m^2	25.0 ± 2.8
AWT, mean ± SD, mm	22.3 ± 7.7
Right side	22.4 ± 7.9
Left side	22.1 ± 7.6
ASA score (%)	
1	5 (9.3)
2	47 (87.0)
3	2 (3.7)
Previous abdominal surgery, n (%)	
Yes	11 (20.4)
No	43 (79.6)
Type of surgery, n (%)	
Left hemicolectomy	2 (3.7)
Anterior resection	37 (68.5)
Low anterior resection	13 (24.1)
Ultra-low anterior resection	2 (3.7)
Estimated blood loss, mean ± SD, ml	55.3 ± 55.1
Operative time, mean ± SD, min	116.9 ± 28.1
Length of hospital stay, mean ± SD, days	7.8 ± 2.4
Postoperative wound complications	
Infection	0
Hematoma	0
Herniation	0

SD, standard deviation; BMI, body mass index; AWT, abdominal wall thickness; ASA, American Society of Anesthesiologists.

Conversely, there were no significant differences in closure time between the suturing device and the hand suture method in patients with BMI < 25 kg/m^2. According to AWT, the closure time with the suturing device was significantly shorter than that with hand suture in patients with 20 ≤ AWT < 26 mm (n = 12, 81.1 ± 11.5 vs. 142.3 ± 83.7 s, $p = 0.023$) and those with AWT ≥ 26 mm (n = 17, 85.6 ± 22.6 vs. 160.2 ± 55.5, $p < 0.001$). No significant

Table 2.
Comparison Between EZ-Close™ *(Right Side)* and Hand Suture *(Left Side)*

Variables	EZ-Close™	Hand Suture	*p*
AWT, mean ± SD, mm	22.4 ± 7.9	22.1 ± 7.6	0.153
Number of attempts, mean ± SD	1.1 ± 0.2	1.1 ± 0.3	0.742
Success of closure, n (%)			<0.001
Yes	47 (87)	27 (50)	
No	7 (13)	27 (50)	
Closure time, mean ± SD, s	87.9 ± 21.0	128.0 ± 59.0	<0.001

SD, standard deviation; AWT, abdominal wall thickness.

Table 3.
Differences in Body Mass Index and Abdominal Wall Thickness Between Failure and Success Groups for Closure in the Left Port Side

Variables	Failure (n = 27)	Success (n = 27)	*p*
BMI, mean ± SD, kg/m^2	25.9 ± 2.9	24.5 ± 2.6	0.036
AWT, mean ± SD, mm	26.7 ± 7.8	17.9 ± 4.4	<0.001

SD, standard deviation; BMI, body mass index; AWT, abdominal wall thickness.

differences in closure time were found between groups in patients with AWT < 20 mm.

DISCUSSION

In this study, a novel device was evaluated with a focus on effectiveness and safety according to the patients' obesity. We compared right-side port closure using EZ-Close™ with left-side port closure using hand suture in identical patients. The patient characteristics were the same between the two groups in terms of demographics. The mean thickness of the right and left sides of the abdomen showed no statistical difference (22.4 ± 7.9 vs 22.1 ± 7.6 mm, $p = 0.153$). Therefore, it was considered that both port sites had the same conditions for suturing.

The use of the newly developed suture device resulted in a significantly lower failure rate than the use of hand suture (13% vs 50%, $p < 0.001$) because most of the failure cases in the hand suture method exceeded the time limit (defined as a maximum of 120 s). In **Figure 2**, the longest closure time of for any EZ-Close™ procedure was 150 s, whereas hand suture took more than 150 s in 10 cases, with the longest closure time being 356 s.

In failure cases in the EZ-Close™ group, the trocar site can be closed by the device without using the BERCI fascial closure instrument. However, if the left trocar site cannot be closed by hand suturing, the site should be closed by using the fascial closure device. When we used the fascial closure device in the hand-suturing group, no bowel or intra-abdominal vasculature injury occurred. However, care should be taken at the time of penetration of the fascia and peritoneum using a conventional trocar-site closure device. Although visceral injury due to a laparoscopic device rarely occurs, a case of aortic injury caused by a conventional fascial closure device has been reported.[13] Several conventional instruments designed for trocar-site closure, such as the Carter-Thomason device (CooperSurgical Inc., Trumbull, CT, USA) or BERCI fascial closure, can facilitate wound closure; however, the exposed needle tip has the potential risk of causing visceral injury. The cartridge of EZ-Close™ has two wings that help protect against intraperitoneal organ injury. This is one of the advantages of EZ-Close™ compared with the conventional devices in terms of safety. However, as we did not evaluate conventional devices, the study could not demonstrate objective results. No visceral injury due to EZ-Close™ occurred in this study.

BMI and AWT also showed a high correlation with closure time. In patients with BMI < 25 kg/m^2, the closure time of the suturing device and that of hand suture did not show a significant difference. However, when EZ-Close™ was used in patients with BMI ≥ 25 kg/m^2, the closure time was statistically shorter than that of hand suturing. As can be seen from **Table 4** and **Figure 2**, in patients with higher BMI or thicker abdominal wall, a more significant effect of surgical time reduction was observed with the use of EZ-Close™.

In patients with AWT < 20 mm, the closure time of the suturing device and that of hand suture did not show significant differences. Especially when the abdominal wall was too thin, such as ≤10 mm, it was difficult to use

Table 4.
Difference in Closure Time Between EZ-Close™ and Hand Suture According to Body Mass Index and Abdominal Wall Thickness

Subgroups	n	Closure time, mean ± SD, s		
		EZ-Close™	Hand Suture	*p*
BMI, kg/m^2				
<23	13	94.8 ± 25.8	91.5 ± 23.4	0.223
23–24.9	13	86.3 ± 20.4	112.5 ± 45.5	0.069
25–26.9	15	85.9 ± 19.8	135.6 ± 67.9	0.014
≥27	13	85.1 ± 18.4	150.2 ± 70.6	0.01
AWT, mm				
<16	12	96.7 ± 24.0	102.2 ± 25.2	0.576
16–19.9	13	89.2 ± 22.1	96.4 ± 29.0	0.457
20–25.9	12	81.1 ± 11.5	142.3 ± 83.7	0.023
≥26	17	85.6 ± 22.6	160.2 ± 55.5	<0.001

SD, standard deviation; BMI, body mass index; AWT, abdominal wall thickness.

EZ-Close™. This is because the locations of the holes in the body that served as passages for the anchor needles were predesigned. The angle of the anchor needle is suitable for patients with an AWT of at least 20 mm.

The closure time of the suturing device was almost half that of hand suture in patients with AWT ≥ 20 mm. In addition, we assumed that there was less variation of closure time with EZ-Close™ than with hand suture regardless of BMI and AWT because of the smaller standard deviation value of the mean closure time of the suturing device.

The accuracy and uniformity of wound closure were not evaluated in this study; however, there was no trocar-site herniation in both groups during the short-term follow-up period. As trocar-site hernia rarely occurs, most previous studies evaluating trocar-site closure devices reported no postoperative herniation in a small population of patients.[7,14–15] Trocar-site hernia is associated with obesity, duration of surgery, age, diabetes mellitus, incision enlargement, and wound infection; thus, proper fascial closure is even more essential in patients with those risk factors.[16]

In the current study, the mean closure time of EZ-Close™ was 87.9 ± 21.0 s. This result is comparable to that of previously published studies evaluating conventional suturing devices. According to an *in vitro* study in cadaver models, the mean closure time of the conventional Carter-Thomason system was 133.6 ± 54.6 s.[17] Another study reported that the Carter-Thomason needle technique took an average of 8 min to close two 10-mm port sites, although the time of complete skin closure was counted.[15] However, several recent studies demonstrated that the mean closure time with the Carter-Thomason device was approximately 30–50 s.[7,14] Even if the same conventional device was used in each study, the significant difference in closure time was probably due to the different criteria for measuring the suture time or the difference in the surgeon's skill level. In our study, all of the wound closure procedures were performed by 3rd and 4th year general surgical residents who had no previous experience with EZ-Close™. This device might be easily handled by beginners, such as the level of a resident surgeon.

The current study has several limitations. First, it included a small number of patients. Second, we did not evaluate the comparison between the novel device and a conventional device such as Carter-Thomason system. Several previous studies were designed to compare the conventional Carter-Thomason device with the various novel trocar-closure systems.[7,14,17] However, in this study we used the hand suturing method for the control group because the majority of trocar site closures in laparoscopic colorectal surgery are performed by hand suturing in South Korea, including in our institution. Thus, we focused on the comparison of EZ-Close™ with manual closure in terms of time efficiency according to the BMI stratification. EZ-Close™ is now covered by our National Health Insurance Service, whereas the price of Carter-Thomason device is not confirmed. Further study should include a cost analysis and comparison with conventional device. Nevertheless, this study has clinical significance in that it analyzed the degree of effectiveness of

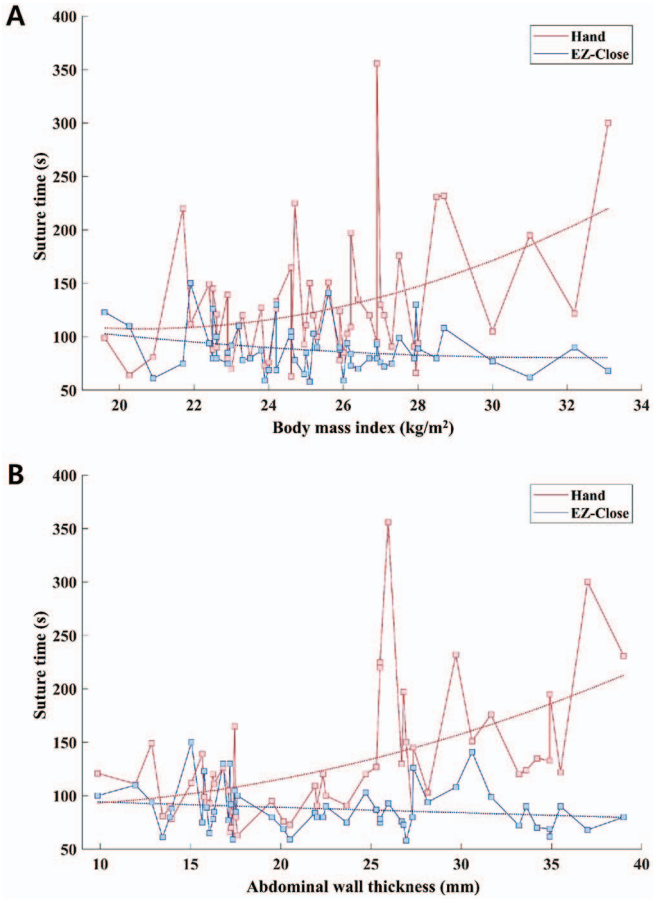

Figure 2. Graph of closure time with EZ-Close™ and hand suture according to **(A)** body mass index and **(B)** abdominal wall thickness.

EZ-Close™ compared with that of hand suture according to the patients' obesity.

CONCLUSION

According to the results of the study, EZ-Close™ was shown to be an effective procedure that reduced the time of the procedure when compared to than hand suture in trocar-site closure, especially in obese patients.

References:

1. Clinical Outcomes of Surgical Therapy Study Group, et al. A comparison of laparoscopically assisted and open colectomy for colon cancer. *N Engl J Med*. 2004;350:2050–2059.

2. Lacy LAM, et al. Laparoscopy-assisted colectomy versus open colectomy for treatment of non-metastatic colon cancer: a randomised trial. *Lancet*. 2002;359:2224–2229.

3. Leung KL, et al. Laparoscopic resection of rectosigmoid carcinoma: prospective randomised trial. *Lancet*. 2004;363:1187–1192.

4. Zhuang CL, et al. Laparoscopic versus open colorectal surgery within enhanced recovery after surgery programs: a systematic review and meta-analysis of randomized controlled trials. *Surg Endosc*. 2015;29:2091–2100.

5. Erdas E, et al. Incidence and risk factors for trocar site hernia following laparoscopic cholecystectomy: a long-term follow-up study. *Hernia*. 2012;16:431–437.

6. Helgstrand F, Rosenberg J, Bisgaard T. Trocar site hernia after laparoscopic surgery: a qualitative systematic review. *Hernia*. 2011;15:113–121.

7. Iranmanesh P, et al. Trocar site closure with a novel anchor-based (neoClose((R))) system versus standard suture closure: a prospective randomized controlled trial. *Surg Endosc*. 2020;34:1270–1276.

8. Wells A, et al. Laparoscopic surgeons' perspectives on risk factors for and prophylaxis of trocar site hernias: a multispecialty national survey. *JSLS*. 2019;23.

9. Muysoms FE, et al. European Hernia Society guidelines on the closure of abdominal wall incisions. *Hernia*, 2015;19:1–24.

10. Swank HA, et al. Systematic review of trocar-site hernia. *Br J Surg*. 2012;99:315–323.

11. Tonouchi H, et al. Trocar site hernia. *Arch Surg*. 2004;139:1248–1256.

12. World Health Organization. Regional Office for the Western Pacific. The Asia-Pacific perspective: redefining obesity and its treatment. Available at: https://apps.who.int/iris/bitstream/handle/10665/206936/0957708211_eng.pdf?sequence=1&isAllowed=y, Accessed February, 2000.

13. Lee G, et al. Aortic puncture with a laparoscopic fascial closure device. *Obstet Gynecol*. 2007;110:533–535.

14. Kim HY, Lee SJ. Prospective randomized control study on the efficiency and safety of a novel port-site closure device, the EZ-Close port-site closure system. *Surg Laparosc Endosc Percutan Tech*. 2019;29:335–338.

15. Shetty A, Adiyat KT. Comparison between hand suture and Carter-Thomason needle closure of port sites in laparoscopy. *Urol J*. 2014;11:1768–1771.

16. Nofal MN, et al. Characteristics of trocar site hernia after laparoscopic cholecystectomy. *Sci Rep*. 2020;10:2868.

17. del Junco M, et al. Evaluation of a novel trocar-site closure and comparison with a standard Carter-Thomason closure device. *J Endourol*. 2014;28:814–818.